

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

FEDERAL TRADE COMMISSION,)	
)	
Plaintiff,)	
v.)	
)	Civ. No. 04-11136-GAO
DIRECT MARKETING CONCEPTS, INC., et al.,)	
)	
Defendants.)	

**MEMORANDUM IN SUPPORT OF PLAINTIFF FEDERAL TRADE COMMISSION'S
MOTION FOR A MODIFICATION OF THE JUNE 23, 2004 PRELIMINARY
INJUNCTION AS TO DEFENDANTS DIRECT MARKETING CONCEPTS, INC.,
ITV DIRECT, INC., AND DONALD W. BARRETT
AND REQUEST FOR EXPEDITED TREATMENT**

I. INTRODUCTION

Plaintiff Federal Trade Commission ("FTC" or "Commission") submits this memorandum in support of its motion to prevent defendants Donald W. Barrett ("Barrett"), Direct Marketing Concepts, Inc. ("DMC"), and ITV Direct, Inc. ("ITV") from continuing to harm consumers by disseminating false and unsubstantiated advertising. Specifically, by continuing to produce and disseminate new infomercials for dietary supplements such as "Sea Vegg" and "Renuva" that make false or unsubstantiated health and disease claims, Barrett, DMC, and ITV (hereafter "Defendants") have not only continued to engage in fraudulent practices, but also have breached their commitment to this Court that they would no longer run infomercials for ingestible products. Defendants' conduct defeats the underlying purposes of the Court's June 23, 2004 Preliminary Injunction as to Defendants Direct Marketing Concepts, Inc., ITV Direct, Inc., and Donald W. Barrett ("Preliminary Injunction") and should be halted.

Additionally, Defendants have: 1) continued to use the faux talk show format about which the Court previously expressed substantial concern; 2) failed to ensure that their sales representatives comply with the Preliminary Injunction by providing the required disclosures to consumers before signing them up for continuity packages; and 3) allowed distributors to establish websites that make similar disease claims for their products. Defendants are also actively seeking to expand these distributor networks. In short, despite having had every opportunity over the past nine months to clean up their business practices, Defendants have chosen to continue misleading and defrauding consumers.

Accordingly, the Commission requests that the Court find that the public injury resulting from Defendants' continued deceptive practices warrants further action to protect consumers during the pendency of this litigation. Specifically, the Commission requests that the Court modify the Preliminary Injunction to appoint a receiver over DMC and ITV for the remainder of the litigation.

II. STATEMENT OF FACTS

A. Background

On June 1, 2004, the Federal Trade Commission commenced this case by filing a complaint alleging that Defendants (and others named in the complaint) were making false and unsubstantiated disease prevention, treatment, and cure claims in advertising for two dietary supplements, Coral Calcium Daily and Supreme Greens; were utilizing a deceptive format in their infomercials for those products; and were billing consumers' credit cards without authorization. The Commission simultaneously moved for a temporary restraining order enjoining DMC, ITV and Barrett from, *inter alia*, representing that any product, program, or

service “can prevent, treat, or cure any disease,” from using deceptive formats that represented to consumers that their infomercials were something other than paid advertising, and from selling products through continuity programs without first obtaining consumers’ express informed consent.

Defendants’ opposition to the Commission’s request for preliminary relief ultimately included three affidavits by Barrett (the President of both DMC and ITV), the third of which stated that:

In light of the FTC’s continuing concerns over the Supreme Greens with MSM infomercial and other infomercials involving ingestible products, *ITV determined several weeks ago that it would no longer produce or air any infomercials involving ingestible products.* As of the date of this affidavit, I am unaware of any infomercial for any ingestible product that is being aired by ITV or DMC, and ITV, DMC and *I have no plans to run any such infomercial in the future.*

Declaration of Christina E. Turner, Attachment 20 at ¶ 12 (emphasis added) (“Turner Dec.”) (Exhibit A to the Commission’s Motion).¹

In response to the Commission’s allegations and supporting evidence that Defendants caused consumers to incur unauthorized charges on their credit or debit cards by enrolling them in autoshop (*i.e.*, continuity) programs without their consent, Barrett informed the Court that in late 2003 – after the Commission’s investigator had been placed on an autoshop program without her prior consent – ITV had implemented a computerized system called “Contract Genie” that

¹ Although the Commission did not know it at the time, internal company documents show that this statement raised some eyebrows within ITV. Specifically, one day before Barrett’s Supplemental Affidavit was submitted to the Court, an ITV employee wrote to ITV’s Director of Operations (who happens to be Donald Barrett’s sister), that “[Y]ou might want to be careful about this statement in light of the fact that ITV’s Vice President of Business Development is in current negotiations for an ingestible product. Clearly the policy change regarding products of interest to ITV has not been communicated throughout the organization.” Turner Dec., Att. 30.

“records each conversation and confirms that the terms of the autoship program are clearly communicated and affirmative assent is obtained.” *Id.*, Att. 19 at ¶ 21. The strong implication of his statement was that unauthorized autoships could not occur anymore.

On June 23, 2004, the Court issued the Preliminary Injunction, in which it specifically found that “Defendants have made the claims that Supreme Greens can cure, treat or prevent cancer, diabetes, arthritis and heart disease” and that the Commission “is likely to prevail in demonstrating the falsity and/or lack of substantiation of these claims. . . .” Preliminary Injunction at 11. The Court therefore enjoined Defendants from representing that “Supreme Greens with MSM or any substantially similar product . . . can prevent, treat, or cure any disease unless, at the time the representation is made, the Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.” *Id.* at 17-18.²

With respect to the format of the Supreme Greens infomercial, the Court found that the ad featured Barrett and Supreme Greens developer Alejandro Guerrero “in a setting that mimics a conventional talk show. . . .” *Id.* at 2. The Court also concluded that “the airing of the infomercial for Supreme Greens in a talk-show format with only limited disclaimers before and after the broadcast is likely to mislead consumers and constitute a deceptive act or practice in violation of Section 5.” *Id.* at 12. Accordingly, it prohibited the Defendants from “creating, producing, selling, or disseminating . . . [a]ny advertisement that misrepresents, expressly or by implication, that it is not a paid advertisement.” *Id.* at 18.

² A “substantially similar product” is defined as any dietary supplement containing one or more of the ingredients contained in the proprietary blend of Supreme Greens with MSM. Preliminary Injunction at 15.

Finally, the Court found that Defendants had caused consumers to incur unauthorized charges on their credit cards by enrolling them without their prior approval in an automatic shipment program (*i.e.*, continuity program or “autoship” program) for a supplement called E-8 Daily when they ordered Supreme Greens. *Id.* at 8.³ The Court found that “defendants maintain they have taken steps to prevent recurrence of such unauthorized charges.” *Id.* The Court enjoined them from selling products through continuity programs without “first obtaining the express, informed consent of consumers” to participate in the program, and ordered them to disclose all material terms of the program. *Id.* at 20-21.

B. Overview of Defendants’ New Infomercials

Since the issuance of the Preliminary Injunction, Defendants have produced or disseminated at least five new infomercials. Four of those infomercials promote the sale of ingestible products through health claims. Most important, at least three of the four infomercials for ingestible products continue Defendants’ practice of making outrageous disease prevention or treatment claims or health benefit claims.⁴ Several of the infomercials also use the same faux

³ Since the issuance of the Preliminary Injunction, the Commission has had access to Defendants’ database and has discovered that it contains many thousands of records referencing customers complaining about being placed on Defendants’ autoship programs without their authorization. Turner Dec., ¶ 40 and Att. 31. Such an astonishing number of complaints makes it very clear that Defendants’ unauthorized billing practices were deliberate, and not atypical or random occurrences.

⁴ The fourth such infomercial, Dr. Day’s Home Juice Bar, began airing in late January 2005, according to the Infomercial Monitoring Service. Turner Dec., ¶¶ 7, 15 and Att. 6. The program promotes three products – Barley Greens, Beta Carrot, and Beta Beet – which come as a powder that is mixed with fluids and drunk, or as a capsule, and purportedly counter the effects of eating conventionally-produced, nonorganic, pesticide-laden food. *Id.* at ¶ 14 and Att. 1 (Dr. Day media file), 11. The infomercial features Barrett and the marketer of these products, Dr. Lorraine Day. Although the infomercial uses similar scare tactics about illness, the direct disease prevention and treatment claims about the product are more vague.

This is not Defendants’ first infomercial with Dr. Day. In October 2004, the National

talk show format as the Supreme Greens infomercial, with Barrett “interviewing” his “guest.”

1. “Sea Vegg” [False claims and deceptive format]

Defendants waste no time making disease treatment and prevention claims in this infomercial, which also uses the talk show format and provides a toll-free number for consumers to purchase Sea Vegg, a dietary supplement containing sea vegetation. Indeed, the claims begin with Barrett’s introduction of his “guest”:

DONALD BARRETT: This half an hour, again, we’re going to be talking about health. If you’re out there and you suffer from cancer, arthritis, diabetes, fibromyalgia, really any chronic degenerative disease, or if you don’t want to get a chronic degenerative disease, this is a show you’re not going to want to miss. On our show today we have Scott Kennedy, who’s a firm believer that most chronic degenerative diseases can be prevented and reversed from nutrients that come from the ocean. We have a very controversial show, so stay with us.

Turner Dec., ¶ 6 and Att. 1 (Sea Vegg media file), 2 at 3-4.⁵ The infomercial then states that eating seaweed has made Mr. Kennedy so healthy that he no longer carries health insurance, that seaweed’s benefits are scientifically proven, that seaweed helped Mr. Kennedy’s mother’s multiple sclerosis, and that eating seaweed is the single most important thing people should do if they want to live a “healthier, happier, disease-free life.” *Id.*, Att. 2 at 33. According to the Infomercial Monitoring Service (“IMS”), which monitors 39 national cable stations and reports the 100 most frequently aired infomercials each month, Sea Vegg (which began running on

Advertising Division of the Better Business Bureau – the advertising industry’s self-regulatory forum – concluded that an ITV infomercial featuring Barrett and Dr. Day that promoted a videotape by Dr. Day entitled “Cancer Doesn’t Scare Me Anymore” made unsubstantiated claims, including the claim that “chemotherapy doesn’t work for anybody.” Turner Dec., Att. 29.

⁵ Notably, Barrett’s opening lines in this infomercial are remarkably similar to those he used to open the Supreme Greens infomercial: “Dr. Guerrero claims that most chronic degenerative diseases -- such as cancer, arthritis, diabetes, even the number one killer out there, heart disease -- can and are being cured and there are natural healing techniques being suppressed in this country. We have a very controversial show, so stay with us.” Complaint Ex. 6 at 3-4.

February 2, 2005) was ranked number 67 in February 2005, number 28 in March 2005, and number 26 in April 2005. *Id.*, ¶ 9 and Att. 3-5.

2. “Renuva” [False claims and deceptive format]

In January 2005, ITV Direct began purchasing air time for a new client: the Renuva Anti-Aging System. Turner Dec., ¶ 13 and Att. 10.⁶ The Renuva system consists of two products – a sublingual spray and a powder that is mixed into a beverage and ingested. *Id.*, Att. 9 at 15-16. The infomercial makes numerous claims about Renuva’s ability to stimulate the body’s production of human growth hormone (“HGH”) and about the benefits that result from those increased HGH levels, including increased energy, improved memory and clarity of thought, and thicker hair. *Id.* at ¶ 12 and Att. 8, 9 at 5, 16-17. The Infomercial Monitoring Service reports that the Renuva infomercial was the 53rd most frequently aired infomercial in January 2005, number 19 in February 2005, number 44 in March 2005, and number 39 in April 2005. *Id.* at ¶ 10 and Att. 3-6. Barrett does not appear in this infomercial, which features celebrity George Hamilton and former Olympic gymnast Cathy Rigby. *Id.*, Att. 9 at 7.

3. “RegenaLife” [Suspect claims and deceptive format]

The RegenaLife infomercial, which appears to have begun running on or about February 26, 2005 (Turner Dec., ¶ 19 and Att. 4), also uses the faux talk show style to promote a multi-ingredient dietary supplement. *Id.* at ¶ 18 and Att. 1 (RegenaLife media file), 13. Barrett opens this infomercial by telling viewers that they are probably going to die from one of several named diseases, unless they follow the advice of his guest:

DONALD BARRETT: Let’s face it, most of us don’t eat right, yet we know we

⁶ Defendants apparently also provide credit card processing services for Renuva orders and ship product to customers. Turner Dec., ¶ 25.

need to. The vast majority of people out there are going to die of some chronic degenerative disease, such as cancer, diabetes, arthritis, even heart disease. These diseases can be directly related to what we eat and what we're exposed to in our environment. . . . The fact of the matter is, folks, most of us are not going to change how or what we eat.

My next guest says there's something out there that's easy, simple and effective that we can do and he can prove it.

Id., Att. 13 at 3-4.

4. "Aquasana" [Deceptive format]

Finally, ITV's infomercial for the Aquasana water filter system, which IMS first detected running on January 18, 2005 (Turner Dec., ¶ 17 and Att. 6) also uses ITV's standard faux talk show format, including an ominous warning in Barrett's opening statement about the "poisoning of our water supply" and the "controversial" nature of the programming viewers are about to see. *Id.*, Att. 12 at 3. The infomercial then goes on to link the deterioration of the American water system and the rise of disease, and to tout the ability of the Aquasana system to remove chemical contaminants from tap and shower water.

III. DEFENDANTS' NEW INFOMERCIALS MAKE FALSE OR UNSUBSTANTIATED HEALTH CLAIMS

A. At Least Two of Defendants' New Dietary Supplement Infomercials Make False or Unsubstantiated Disease and/or Health Claims

1. Sea Vegg

Defendants' infomercial represents that Sea Vegg, a product containing dried seaweed, can prevent or treat serious degenerative diseases, including cancer, arthritis, diabetes and fibromyalgia.⁷ The Sea Vegg infomercial includes the following statements:

⁷ Trial courts, as finders of fact, may draw reasonable inferences and make factual determinations as to both the express claims and the implied claims that are conveyed by the face

DONALD BARRETT: . . . If you're out there and you suffer from cancer, arthritis, diabetes, fibromyalgia, really any chronic degenerative disease, or if you don't want to get a chronic degenerative disease, this is a show you're not going to want to miss. On our show today we have Scott Kennedy, who's a firm believer that most chronic degenerative diseases can be prevented and reversed from nutrients that come from the ocean. We have a very controversial show, so stay with us.

SCOTT KENNEDY: [The drug companies] come right out and say they want to turn cancer into a chronic and manageable disease. No, thank you. I don't want to turn cancer into a manageable disease. I want it out of my life, out of family's life and I want it to go away like it used to be a way and --

DONALD BARRETT: But have you seen that happen? You've been studying the problems for years.

SCOTT KENNEDY: I have seen it --

DONALD BARRETT: Have you seen that happen?

SCOTT KENNEDY: I've seen the Japanese. If anybody just goes online or in the library, they can study it. For some reason, the information is curiously missing from this country.

DONALD BARRETT: You're saying the information is being suppressed in this country?

SCOTT KENNEDY: It's not being given to us by health professionals who are drug-based health professionals. . . .

SCOTT KENNEDY: . . . I haven't had a cold, flu or fever in -- since 1992. I stopped carrying health insurance. I have an accident policy. Why? Because my pH is balanced with seaweed. . . .

DONALD BARRETT: No health insurance?

of an advertisement. *See FTC v. Febre*, No. 94 C 3625, 1996 WL 396117, at *4 (N.D. Ill. July 3, 1996) (magistrate judge recommendation), *adopted by* 1996 WL 556957 (N.D. Ill. Sept. 27, 1996), *aff'd*, 128 F.3d 530 (7th Cir. 1997). *See also Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 652 (1985); *FTC v. Gill*, 71 F. Supp.2d 1030, 1043 (C.D. Cal. 1999), *aff'd*, 265 F.3d 944 (9th Cir. 2001).

SCOTT KENNEDY: In my lifetime -- in 20 years, everybody's gotten sicker and I've gotten healthier and I'm a proponent for eating seaweed every day in America and we're the only company that does this responsibly, has the science behind it and I've been at it 21 years.

SCOTT KENNEDY: . . . [i]n the meantime, all I want to do is get seaweed to your viewers, help people get healthier, like I did my mother and my sisters and my friends and my family and help their pets and help their children.

DONALD BARRETT: If somebody's sick, if they have some chronic degenerative disease, cancer, arthritis, diabetes, fibromyalgia, all the diseases that are running rampant right now --

SCOTT KENNEDY: Um-hum.

DONALD BARRETT: -- should they take more than three capsules a day?

SCOTT KENNEDY: Let me put it in perspective for you. The Japanese people, as a culture, from studies -- and some of the studies are over here and over here -- eat an average of seven grams a day. That's over a bottle of this. So, don't worry about OD'ing. And if they have diseases or they have something they're concerned with, they should consult their physician.

DONALD BARRETT: Unfortunately, we're running out of time. We will have you back. But if there's one thing that somebody can do out there to live a healthier, happier, disease-free life, what would you recommend?

SCOTT KENNEDY: If there's one thing anyone can do every day that can have the most beneficial impact on their health and the possibility of regeneration it's eating whole marine algae, especially blends of it like we have in our Sea Vegg every single day. ...

DONALD BARRETT: You sound so confident.

SCOTT KENNEDY: Well, I've been on it for 20 years and I've seen so much. I can't even explain what I've seen. I've got testimonials and letters and tapes. You wouldn't believe what I've heard. In fact, I thought it was miraculous when it helped my mother's MS. But what I've seen since then, you wouldn't believe that one type of supplement could do all these things. . . .

Turner Dec., Att. 2 at 3, 10-11, 20, 26, 28, 30, 33-34.

Defendants even go so far as to represent that scientific research establishes Sea Vegg's efficacy in disease prevention:

DONALD BARRETT: But there's scientific research to back up what you're saying?

SCOTT KENNEDY: I wouldn't be on your show today if I didn't have that research. In fact, the science is king with me. It's not my opinion. I'm just the messenger, and I'm not here to prove that seaweed works. It's already been proven.

Id. at 19.

Sea Vegg also purportedly enables users to lose weight effortlessly, by reducing food cravings:

DONALD BARRETT: Weight loss? Fifty percent of our population is now considered obese --

SCOTT KENNEDY: Um-hum.

DONALD BARRETT: -- by medical standards.

SCOTT KENNEDY: Yes.

DONALD BARRETT: Could this help people lose weight?

SCOTT KENNEDY: The answer is this, when people take Sea Vegg every day, it will normalize their weight and begin to normalize their thyroid. People that are too underweight will gain weight and women that are overweight will begin to lose some pounds and inches right away without even trying.

DONALD BARRETT: So, by taking the Sea Vegg, it will bring you to your -- the weight that you should be at?

SCOTT KENNEDY: Yes, despite your eating habits. Then your cravings will begin to change and your weight will change and sugar -- your cravings for sugar and certain things that aren't good for you --

Id. at 32-33. Indeed, the combination of disease prevention and treatment claims and weight loss claims is strongly reminiscent of the Supreme Greens infomercial.

These claims are not substantiated by competent and reliable scientific evidence. The Commission has provided the declaration of Christine Skibola, Ph.D., that expresses the well-supported opinion that the above claims are either false or not supported by reliable scientific evidence. Declaration of Christine Skibola, Ph.D., In Support of The Federal Trade Commission's Motion for a Modification of the June 23, 2004 Preliminary Injunction, ¶ 27 (Exhibit B to the Commission's Motion). Dr. Skibola is a Research Toxicologist in the Molecular Epidemiology and Toxicology Laboratory, which is in the Department of Environmental Health Sciences at the University of California at Berkeley's School of Public Health. *Id.* at ¶ 1. She has conducted research into the health benefits of seaweed and is familiar with the existing research in this area. *Id.* at ¶¶ 15, 19, 22-23. Although seaweed is a nutritious food that contains fiber, minerals, and other beneficial nutrients, Dr. Skibola states that there is no reliable scientific evidence to support the strong claims in the Sea Vegg infomercial – namely that any varieties of seaweed, including those in Sea Vegg, treat or prevent cancer, fibromyalgia, diabetes or arthritis or cause weight loss. *Id.* at ¶¶ 20-25.

Indeed, the limited epidemiological studies – which in and of themselves do not prove treatment efficacy or prevention – suggest mixed results, with some finding that seaweed consumption is associated with lower rates of colorectal and endometrial cancers, but other studies finding that it is associated with higher rates of prostate and stomach cancer. *Id.* at ¶ 21. As for weight loss, in one reported 2-year study, no meaningful weight loss was observed in twenty-four moderately overweight women who took a kelp-lecithin-vitamin supplement for over two years. *Id.* at ¶ 25. At best, there are some studies of seaweed finding *limited* positive health benefits. *Id.* at ¶ 20. According to the Commission's expert, therefore, there is no reliable, scientific evidence supporting Defendants' claims for Sea Vegg.

2. Renuva

The infomercial presents Renuva, a system of ingestible products, as the solution to the problem of aging:

MALE ANNOUNCER: [N]ow, you can experience more energy and the phenomenal wonders of increasing your levels of HGH.

Introducing the Renuva System, a revolutionary two-part system that could turn back the clock five, 10, even 15 years or more on the way you look and feel, guaranteed. And it's so easy.

Turner Dec., ¶¶ 11, 12 and Att. 8, 9 at 14-15. The problem, according to the infomercial, is that our body's production of growth hormone drops substantially in adulthood, causing our bodies to age:

**ON SCREEN: Hgh
Master Hormone**

MALE ANNOUNCER: Because it affects virtually every cell in your body, it has been called the master hormone.

ON SCREEN: Hgh is Vital

- Energy
- Cell Repair
- Brain function
- Muscle growth
- Bone strength
- Healing
- Metabolism

MALE ANNOUNCER: Unfortunately, in our twenties, our level of HGH begins to plummet so that by age 60, we've lost 80 percent or more. And with this loss, the things we hate about aging start to happen, loss of energy, sagging skin, weight gain, loss of sex drive, motivation, memory.

Id., Att. 9 at 30-31. The ad goes on to tout the proven benefits of human growth hormone:

**ON SCREEN: Research on Hgh
Most studies mentioned were conducted with medically prescribed injectible HGH.**

- Increased Energy and Stamina
- Decreased Weight and Body Fat
- Restored Muscle Mass
- Reduction of Aches and Pains
- Improved Quality of Sleep
- Thicker Skin, Fewer Wrinkles
- Increased Calmness, Less Stress
- Improved Memory
- Increased Sexual Drive
- Faster Recovery from Exercise
- Improved Cholesterol Levels
- Enhanced Metabolism
- Better Ability to Concentrate
- Improved Vision
- Improved Immune System

Id. at 31-32. The Renuva system purportedly provides those same benefits:

GEORGE HAMILTON: [W]hen you take the nutrition base of the Renuva Generator and add that to the activating process of Renuva Infuser, you get what could be the simplest, most effective, non-prescription way to experience the wonders of increased HGH levels ever developed.

ON SCREEN: Dr. Alfred Garbutt, D.C.
Chiropractor/Clinical Nutritionist
Special TV Offer
Renuva
1-800-555-5555

DR. ALFRED GARBUTT, D.C.: This system is real. You know, like you said, there's science behind it that really backs up how it works.

DR. DOUG FRIESEN: People can literally look forward to a 10 to 20-year change of how they look and how they feel.

Id. at 35-36. And celebrity hosts George Hamilton and Cathy Rigby and consumer testimonialists speak glowingly about their experiences using Renuva:

GEORGE HAMILTON: . . . It just makes you feel terrific. I feel like a racing machine, a lean, mean racing machine.

CATHY RIGBY: I don't think I've ever felt better in my life. I really feel the difference in my body. I really feel the difference. It's great to feel good. It's great to feel great at 50.

KAREN SCOTT: A huge difference in my life.

FRANK BAKER: One of the most important things I've ever done.

CYNTHIA DOWNEY: Energy.

PATTI NICKLAUS: Sleeping better.

DANIEL TREVOR: Thinking is so much more clear.

LINDA MARTIN: My memory is a lot better.

AL BEARD: Body's more fit.

KATHY BORNSTEIN: My hair is thicker.

PETER MYERS: Look younger.

TERRY LAWLER: Lost the pot belly.

BRUK VANDEWEGHE: Immediately, the first thing that I noticed is that I had a lot more energy. I also slept a lot better, which made me a lot more motivated to go work out. . . . My skin has gotten a lot clearer. I've been a lot more mentally focused. I found that I wasn't getting as sick as often as other people around me. Usually, I get colds really easily, and since I've been on the Renuva System, I don't get sick as much.

Id. at 5, 16-17, 44-45.

Again, as is the practice of Barrett, DMC and ITV, these claims are not supported by competent and reliable scientific evidence. According to Mary Lee Vance, M.D., a Professor of Medicine and a Professor of Neurosurgery at the University of Virginia Medical School, in order to show that a product or treatment increases the body's growth hormone ("GH") levels, qualified experts would require a double-blind, placebo-controlled clinical trial of human subjects that measured serum GH and insulin-like growth factor-1 ("IGF-1"), the "effector" of GH action. Declaration of Mary Lee Vance, M.D., In Support of The Federal Trade

Commission's Motion for a Modification of the June 23, 2004 Preliminary Injunction, ¶ 12 (Exhibit C to the Commission's Motion).⁸ Additionally, to show that a product or treatment produces benefits such as increased energy and stamina, decreased weight and body fat, increased muscle mass, reduced aches and pains, improved quality of sleep, younger, thicker skin, and fewer wrinkles, improved memory, and increased sex drive, experts would require a long term, double-blind, placebo controlled clinical trial of an adequate number of human subjects based on the listed outcome measures. *Id.* at ¶ 13.

Dr. Vance is not aware of any clinical trial evidence showing that a product containing the ingredients in either Renuva product, when used by healthy adults, will increase GH or IGF-1 levels and/or produce increased energy and stamina, decreased weight and body fat, increased muscle mass, reduced aches and pains, improved quality of sleep, younger, thicker skin, and fewer wrinkles, improved memory, or increased sex drive. *Id.* at ¶¶ 16-17. Indeed, as explained in more detail in her Declaration, there are a few small studies on the benefits of *injected* GH that show mixed results at best. *Id.* at ¶¶ 9, 17. Studies of the effect of injected GH administration cannot be compared to GH that is ingested orally, however, because growth hormone is broken down (degraded) by gastric acid, and thus oral GH or purported GH stimulants supposedly contained in Renuva would not be expected to be effective. *Id.* at ¶ 10. Thus, as is the case with Sea Vegg, Defendants claims for Renuva are not substantiated by reliable scientific evidence.

⁸ Dr. Vance is an expert in the areas of endocrinology, including growth hormone (GH) secretion and the analysis of clinical trials to evaluate potential mechanisms to increase GH levels in adults. Vance Dec., ¶ 3.

B. Defendants' Infomercial for the Ingestible RegenaLife Product Also Makes Suspect Disease and Health Claims

Because of the time required to locate and hire experts and the fact that the Regenalife infomercial just started running in March 2005, the Commission has submitted expert declarations addressing only the Sea Vegg and Renuva infomercials. The Commission has concerns, however, about the validity of the disease prevention or treatment claims made for this latest dietary supplement, a cocktail consisting of, among other things, noni, wolfberry extract, raspberry, clove, kale, spinach, garlic, broccoli, beet, and alfalfa. Turner Dec., Att. 13 at 22. Notably, as discussed below, Barrett takes a particularly commanding role in this infomercial and repeatedly asks his "guest" questions relating directly to disease treatment.

In the infomercial, Dr. Duarte tells Barrett how he transformed himself from a sickly child who faced a lifetime of taking various medications to a healthy adult. *Id.* at 4-5. He then goes on to assert that conventional medicine kills nearly 800,000 people each year – more than die from either cancer or heart disease – so there is a need for "reliable alternatives that people can use for themselves that are cost-effective." *Id.* at 7. In other words, his dietary supplement product will help prevent people from getting the diseases that will force them to turn to dangerous conventional medicine. Furthermore, a superscript that says "**Can the body be healed using all-natural supplements?**" appears on screen throughout most of the infomercial. *Id.*, Att. 1 (RegenaLife media file), 13 *passim*. Barrett repeatedly steers the discussion to disease issues by asking Dr. Duarte questions such as "Now, Dr. Duarte, is there any research out there that Regenalife can actually help people with chronic degenerative diseases?" and "Dr. Duarte, here's the question, if I start taking RegenaLife, am I going to feel a difference? Because I don't feel sick now." *Id.*, Att. 13 at 15, 17. Again, it is difficult to believe that competent and reliable

scientific could substantiate that Regenalife can actually cure or prevent serious, chronic diseases.

IV. DEFENDANTS ARE ALSO ENGAGING IN OTHER BUSINESS PRACTICES THAT ARE PERMEATED BY FRAUD

In addition to their continued dissemination of false or unsubstantiated health claims for dietary supplements, Defendants have also continued since the issuance of the Preliminary Injunction to engage in other conduct that misleads or otherwise injures consumers.⁹

A. Continued Use of Misleading Talk Show Format

Despite the Court's clear concern about their use of a format that "mimics a conventional talk show," Defendants' newly-produced infomercials for Sea Vegg, Aquasana, and RegenaLife all use that same format, with Barrett "interviewing" his "guest," much as the host of a conventional talk show would do. Indeed, Barrett actually refers to this format as "Larry King Live" style – an obvious reference to the well known talk show host. Turner Dec., ¶ 35 and Att. 26. Defendants' inclusion of a few additional disclaimers in these latest infomercials does not alter the misleading nature of their programming.

Barrett further strengthens this misleading impression by telling viewers that they are about to see a "controversial show" about a health topic of tremendous importance and by introducing as his "guest expert" on that topic a person who is actually the marketer of the product being promoted. For instance, the Aquasana infomercial opens with the following

⁹ The Commission could have asked the Court to find Defendants in contempt of the Preliminary Injunction's formatting and autoship requirements but ultimately decided – because a finding of contempt would not have addressed all the ways in which Defendants continue to injure consumers – to ask the Court to address all of Defendants' fraudulent practices comprehensively through the instant motion seeking an order modification to appoint a receiver.